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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,564	01/27/2000	PASCAL CLAUDE MICHEL LOUVEL	P1047/20008	6103

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09/10/2002

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/10/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/402,564

Applicant(s)

LOUVEL ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Receipt is acknowledged of the Extension of Time and the Amendment D, both received by the Office on July 8, 2002.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/14058 to Oshlack *et al.* (hereinafter WO '058). WO '058 teaches a sustained release dosage form comprising a plurality of microparticles produced via melt extrusion techniques (abstract), and WO '058 also discusses the extruder used to make the formulation. WO '058 teaches that the active ingredient in the formulation is in a matrix including a hydrophobic material, such as alkylcelluloses and acrylic polymers, and a hydrophobic carrier (p 6, l 13-30). However, WO '058 further teaches that a plasticizer can also be added to help with the extrusion process (p 10, l 21-26). WO '058 also teaches a method for preparing their formulation, which involves blending the drug with the matrix ingredients, heating the blended mixture, placing the mixture in the extruder, extruding the strands, then dividing the strands into the desired pieces, such as pellets (p 7, l 15-30, and claim 18). WO '058 also teaches that the extruded materials can be cut into multiparticulates by any means known in the art, and they further teach that the multiparticulates can be compressed into tablets (p 8, l 1-2). Lastly, WO '058 teaches that the

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exit port of the extruder can be any desired shape, in order to make the multiparticulates the desired shape and size (p 17, l 23-25). It is the position of the examiner that this disclosure reads on the method of making particles as claimed by applicant.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant's argue that in new claim 9, the mixture in question is subjected to a maturing step carried out outside the extruder at a temperature from 20-70° C which is maintained at least "30 minutes", advantageously in a ventilated tray type oven before being introduced into the extruding machine inside which it is heated to the extrusion temperature and subjected to the extrusion pressure during 2 to 6 minutes. Applicant's further argue that the cited reference does not disclose the heating step outside the extruder and therefore the rejection is not well founded. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., extrusion step which takes place outside the machine....) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, applicant asserts that the examiner has provided no reasoning for why applicant's previous arguments were not found persuasive. The examiner disagrees and directs applicant's attention to page 3, first full paragraph to page 4 and page 5, first full paragraph to page 6.

Additionally, applicant asserts that unexpected results are shown in the specification. First, a showing of unexpected results does not get around a anticipation rejection. Additionally,

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the examiner is still not persuaded by the results of Table I. First, there is no discussion of statistical analysis of the data presented. Absent this information, it is impossible to tell how significant the data really is. Furthermore, the examiner notes that the differences between A1 and A2 do not appear to be statistically significant, although one was subjected to maturation for 4 hours and the other for 2 days. This also appears to be true for B1 and B2 (particularly at 1.5 hours, 2 hours and 8 hours), and C2 and C3. These numbers contradict applicant's assertion that the data proves that increasing the maturation conditions (time and temperature) slows the release rate. Additionally, as stated above, absent the necessary statistical analysis of the data, it is impossible to determine the significance of the numbers presented in table I.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WP 96/14058 to Oshlack *et al.* as discussed above, and in view of the following comments.

Although WO '058 does not teach that the particles are spheroidal, they do teach that the exit port of the extruder can be any shape desired. They further teach that they want to eliminate the spheronization step, which is stated by applicant as well, and it is the position of the examiner that by allowing the exit port of the extruder to be any shape so that the multiparticulates can be of any shape, this allows the exit port to be a shape that would form

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spheroidal particulates. Further, although WO '058 does not specifically refer to a maturing step, it is the position of the examiner that the heating step prior to extrusion, which is discussed by WO '058, reads on applicant's claimed maturing step. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that the heating step relied upon in WO '058 does not teach the maturing step of applicant's claimed process. However, the examiner respectfully disagrees. WO '058 does teach a heating step prior to the extrusion, and applicant's claimed maturing step is simply a heating step with a defined time and temperature. Applicant further argues that the heating step relied upon by the examiner is simply a normal step carried out in an extrusion method, and applicant further argues that this step takes place within the extrusion machine. However, the examiner disagrees as there is no evidence to prove that this heating step, discussed by the prior art, takes place inside the extrusion machine, nor does applicant specify in his claim language that the extrusion step must take place outside the machine.

Lastly, applicant argues that the instantly claimed apparatus is not rendered obvious because the prior art does not teach an extruder comprising a tool for chopping particles as defined by the instant claim. The examiner respectfully disagrees. The cited art teaches that their process eliminates the spheronization step (p 5, l 25). Additionally, the cited art teaches that the extrudate is cut by blades after the melt extrusion process. It is the position of the examiner that the cutting tool claimed by applicant is the equivalent to a typical cutting blade at

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the exit of the extrusion machine. Furthermore, the examiner directs applicants attention to page 17, lines 28-30 of the cited reference. Here, it is taught that the multiparticulate system can be in the form of granules, spheroids, or pellets, depending on the extruder exit orifice. Therefore, absent any evidence to the contrary, it is the position of the examiner that the apparatus of the cited reference renders applicant's cited apparatus obvious, as the cutting step disclosed in the reference also renders spheroids, and therefore, although it is not specified, it must be an equivalent blade setup.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep  
September 9, 2002

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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